

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparision of the effect of probiotics mouthwash and normal saline in the treatment of radiotherapy induced mucositis

#### Protocol summary

##### Study aim

The practical purpose of this study was to introduce probiotic mouthwash as one of the effective treatments in oral mucositis ulcers .

##### Design

Randomized clinical trial with parallel groups, double-blind, phase 2 on 64 patients, Excel software rand function was used for randomization

##### Settings and conduct

In both groups, in addition to the usual treatment of mucositis, probiotic and normal saline mouthwash is started 1 day before the start of radiotherapy. The patient gargles mouthwash three times a day for 3 minutes. The patient and the distributor of mouthwash do not know the type of mouthwash used. Clinical care is provided at Imam Khomeini Hospital.

##### Participants/Inclusion and exclusion criteria

all patients needed head and neck radiotherapy at imam khomeini hospital are eligible for the study.

##### Intervention groups

During radiotherapy, every 3 days for 6 weeks, patients are examined for mucositis by an examination by Dr specialist in oral medicine, and the patient's mucosal grade is determined by a clinical examination by Dr specialist in oral medicine

##### Main outcome variables

The sampling process will take time and the study will be long. The main expected outcome is the positive effect of probiotic mouthwash on patients' oral mucosa.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201106049288N1**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

##### Registration date

2020-12-23, 1399/10/03

##### Registrant information

###### Name

Zahra Mofazzal jahromi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2249 0860

###### Email address

zahramofazzal@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparision of the effect of probiotics mouthwash and normal saline in the treatment of radiotherapy induced mucositis

##### Public title

Effect of probiotics mouthwash and normal saline in treatment of mucositis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

all patients needed head and neck radiotherapy at imam khomeini hospital .

**Exclusion criteria:****Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization method is used. For randomization, randomly selected pre-radiotherapy use is selected for inclusion in the study. The first step in performing a random process is to create a random sequence. The second step after creating a random sequence is sequencing generating technology (property privatization acquisition). The purpose of these steps is to prevent any predictions of future allocation by drug sales and distribution companies. Both groups compete with each other using age and gender, and the age of the people in the case group is controlled by the average age of the people in the control group, and thus matching between the two groups takes place.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In addition to the patient, the person giving the mouthwash to the patient does not know the type of mouthwash.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the School of Dentistry, Tehran University of Medical Sciences

**Street address**

Khani Abad No - Shahid Zolfi St. (Mahan) - Opposite Shariati Park - School of Dentistry

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2020-12-19, 1399/09/29

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1399.176

**Health conditions studied****1****Description of health condition studied**

Radiotherapy-induced oral mucositis

**ICD-10 code**

K00-K14

**ICD-10 code description**

بیماریهای حفره دهانی، غددبزاقی و فک ها

**Primary outcomes****1****Description**

The effect of mouthwash on mucositis

**Timepoint**

Once every 3 days for 6 weeks

**Method of measurement**

Mucosite grading

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Probiotic mouthwash is used to prepare probiotic mouthwash from Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus salivarius, Lactobacillus ruteri, Bifidobacterium lactobacillus, Bactidobacterium lactobacillus, The combination of bacteria is prepared in powder form and is provided to the therapist and the patient as a pre-prepared solution.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: To prepare normal saline mouthwash from Tween 80 (500 mg), 5 (Avicel g) and xanthan (2 g), methyl paraben (8.1 g), propyl paraben (200 mg), disodium hydrogen phosphate (2 g), sodium dihydrogen phosphate (3 g) and distilled water are used.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

بیمارستان امام خمینی

**Full name of responsible person**

دکتر سهیلا مانی فر

**Street address**

بزرگراه چمران، خیابان بافرخان، انتهای بلوار کشاورز، مجتمع  
بیمارستان امام خ

**City**

تهران

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6119 0000

**Email**

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

دکتر مریم کوپایی

**Street address**

خانهی آباد نو - خیابان شهید زلفی (ماهان) - روبروی پارک شریعتی -  
دانشکده دندانپزشکی

**City**

تهران

**Province**

Tehran

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**Email**

dentistryic@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra mofazzal jahromi

**Position**

Dental student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Army Highway, Shahid Mahallati Town, Phase 3,  
Neighborhood 6, Noor 1st St., Yas 3 Block, Unit 5

**City**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam koopaie

**Position**

DDS.MS. Medicine and oral maxillofacial

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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End of Ashrafi Esfahani, Eghbalpour St., 17th East  
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**Province**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra mofazzal jahrromi

**Position**

Dental student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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Tehran

**Postal code**

1955737158

**Phone**

+98 21 2249 0860

**Email**

zahramofazzal@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available